

## PATENT APPLICATION

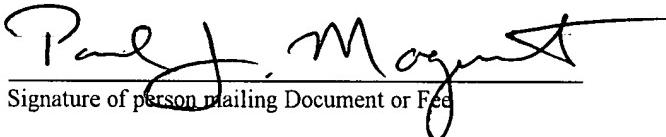
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Paul J. Maginot

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Signature of person mailing Document or Fee

Applicant(s):	Mark A. Heldreth 7140 North 900 East Mentone, Indiana 46539	Deborah S. German 13445 Linwood Drive Plymouth, Indiana 46563
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## PROSTHESIS EVALUATION ASSEMBLY AND ASSOCIATED METHOD

Paul J. Maginot  
Registration No. 34,984  
Attorney Docket No. 1671-0171

Correspondence Address:  
Maginot Addison & Moore  
Bank One Center/Tower  
111 Monument Circle, Suite 3000  
Indianapolis, Indiana 46204-5115  
Telephone: (317)638-2922  
Facsimile: (317)638-2139

## PROSTHESIS EVALUATION ASSEMBLY AND ASSOCIATED METHOD

### Provisional Patent Application

This application claims the benefit of U.S. Provisional Application  
5 Serial No. 60/258,390, filed December 27, 2000, the disclosure of such  
application being totally incorporated herein by reference in its entirety.

### Technical Field of the Invention

The present invention relates generally to a surgical trial instrument  
10 assembly and, more particularly, to a method and apparatus for  
evaluating the stability and kinematic behavior of a mobile bearing knee  
implant prior to commitment to a final preparation of a proximal tibia.

### Background of the Invention

15 During the lifetime of a patient, it may be necessary to perform a  
joint replacement procedure on the patient as a result of, for example,  
disease or trauma. One such type of joint replacement procedure is a  
total knee replacement procedure in which a diseased and/or damaged  
knee joint is replaced with a prosthetic knee joint. A typical total knee  
20 replacement procedure utilizes a prosthesis that generally includes a  
femoral component, a tibial tray, and a tibial bearing insert. The femoral  
component generally includes a pair of laterally spaced apart condylar  
portions, the distal surfaces of which bear against a complementary pair  
of surfaces defined in the tibial bearing insert. The tibial tray typically

includes a plate having a stem extending distally therefrom. The stem is implanted in a prepared medullary canal of the patient's tibia. Once implanted in such a manner, the tibial tray provides a surface on the proximal end of the tibia to which the tibial bearing insert may be affixed.

5 During performance of such a knee replacement procedure, the surgeon must evaluate the size and condition of the patient's bones (e.g., the patient's tibia) in order to determine the proper type and configuration of each of the various types of prosthetic components that are to be implanted. This procedure is known as trialing.

10 Surgeons prefer to check the stability and kinematic behavior of the implant prior to the final preparation of the tibia bone for the final implant. However, current trialing systems require the surgeon to prepare the bone for the final implant prior to checking the stability and behavior of the implant. In particular, current trialing systems require the proximal tibia to  
15 be broached, reamed, punched, or otherwise prepared in order to place an evaluation trial in place. This requires the surgeon to commit to the use of a mobile bearing tibial implant prior to being able to finish their evaluation of stability and kinematic behavior.

What is needed therefore is an apparatus and method for trialing a  
20 tibia implant.

What is further needed therefore is an apparatus and method for evaluating the stability and kinematic behavior of a mobile bearing knee implant during a total knee arthroplasty.

### Summary of the Invention

In accordance with one embodiment of the present invention, there is provided a trial tray assembly for evaluating the stability and kinematic behavior of a prosthetic knee implant prior to implanting the final prosthetic knee implant. The assembly includes a trial tray configured to be placed on a proximal end of a resected tibia, the trial tray having a plate with a configured opening. The assembly further includes an alignment handle detachably couplable to the plate. Moreover, the assembly includes an evaluation bullet having a profile corresponding in shape to the configured opening and removably received in the configured opening, the evaluation bullet including a trunnion adapted to receive a trial insert thereon, the trial insert mimicking the final prosthetic knee implant.

In accordance with another embodiment of the present invention, there is provided a method for evaluating the stability and kinematic behavior of a prosthetic knee implant prior to implanting a final prosthetic knee implant. The method includes the steps of (i) resecting a patient's proximal tibia, (ii) placing a trial tray onto the resected proximal tibia, the trial tray defined by a plate having a configured opening therein, (iii) placing an evaluation bullet into the configured opening, the evaluation bullet shaped to substantially conform to the configured opening and having a trunnion, (iv) placing an insert trial mimicking the final prosthetic

knee implant having a recess therein onto the trunnion, and (v) moving the tibia to determine stability and kinematics of the insert trial.

In accordance with yet another embodiment of the present invention, there is provided an apparatus for evaluating the stability and 5 kinematic behavior of a prosthetic knee implant before final implant of a prosthetic knee implant. The apparatus includes a trial tray having a configuration substantially corresponding to a shape of a resected tibia and including a cutout portion. The apparatus further includes a handle adapted to be removably attached to the trial tray. Moreover, the 10 apparatus includes an evaluation bullet shaped to be removably received in the cutout portion and including a trunnion. Also, the apparatus includes a trial insert having a recess adapted to be removably received on the trunnion.

Pursuant to another embodiment of the present invention, there is 15 provided a prosthesis evaluation assembly which includes a tray configured to be supported on a proximal end of a resected tibia, the tray having an opening defined therein. The prosthesis evaluation assembly further includes an evaluation member having (i) a lower portion configured to be received within the opening, and (ii) an upper portion 20 configured to support a trial insert thereon.

In accordance with yet another embodiment of the present invention, there is provided a prosthesis evaluation assembly. The assembly includes a tray configured to be supported on a proximal end of

a resected tibia, the tray having an opening defined therein. The assembly also includes an evaluation member having (i) a tray contact portion configured to be received within the opening, and (ii) an insert contact portion. In addition, the assembly includes a trial insert having a

5 recess configured to receive the insert contact portion.

It is therefore an object of the present invention to provide a new and useful surgical assembly for evaluating the stability and kinematic behavior of a trial prosthetic implant prior to final prosthetic implant.

It is moreover an object of the present invention to provide an

10 improved surgical assembly for evaluating the stability and kinematic behavior of a trial prosthetic implant prior to final prosthetic implant.

It is a further object of the present invention to provide a new and useful method of surgically evaluating the stability and kinematic behavior of a trial prosthetic implant prior to final prosthetic implant.

15 It is also an object of the present invention to provide an improved method of surgically evaluating the stability and kinematic behavior of a trial prosthetic implant prior to final prosthetic implant.

The above and other objects, features, and advantages of the present invention will become apparent from the following description and

20 the attached drawings.

Brief Description of the Drawings

Fig. 1 is a perspective view of a trial tray and handle incorporating features in accordance with the principles of the present invention;

Fig. 2 is a top view of the trial tray and handle of Fig. 1 situated on  
5 a proximally resected tibia in accordance with the principles of the present invention;

Fig. 3 is a top plan view of an embodiment of a lock-out evaluation bullet in accordance with the principles of the present invention;

Fig. 4 is a bottom plan view of the lock-out evaluation bullet of Fig.  
10 3;

Fig. 5 is a side plan view of the lock-out evaluation bullet of Fig. 3 taken along line 5-5 thereof;

Fig. 6 is a side plan view of the lock-out evaluation bullet of Fig. 3 taken along line 6-6 thereof;

15 Fig. 7 is a sectional view of the trunnion of the lock-out evaluation bullet of Fig. 6 taken along line 7-7 thereof;

Fig. 8 is a top plan view of an embodiment of a pinned, rotational evaluation bullet in accordance with the principles of the present invention;

20 Fig. 9 is a bottom plan view of the pinned, rotational evaluation bullet of Fig. 8;

Fig. 10 is a side plan view of the pinned, rotational evaluation bullet of Fig. 8 taken along line 10-10 thereof;

Fig. 11 is a side plan view of the pinned, rotational evaluation bullet of Fig. 8 taken along line 11-11 thereof;

Fig. 12 is a sectional view of the trunnion of the pinned, rotational evaluation bullet of Fig. 11 taken along line 12-12 thereof;

5 Fig. 13 is a front perspective view of the present trial tray and handle situated on the resected tibia and accepting the lock-out evaluation bullet; and

Fig. 14 is a side view of the present trial tray, handle and lock-out evaluation bullet of Fig. 13 on the resected tibia accepting a tibial insert

10 trial;

Fig. 15 is a front perspective view of the present trial tray, handle and lock-out evaluation bullet between the resected tibia and femur of fig. 13 for rotational alignment thereof;

15 Fig. 16 is a front perspective view of the present trial tray and handle situated on the resected tibia and accepting the pinned, rotational evaluation bullet;

Fig. 17 is a front view of the present trial tray and tibial insert trial of Fig. 13 on the resected tibia;

20 Fig. 18 is a front view of the present trial tray and tibial insert trial of Fig. 13 between the tibia and femur for evaluating rotation thereof;

Fig. 19 is a perspective view of the present trial tray without an evaluation bullet being secured to the resected tibia for final implant; and

Fig. 20 is a perspective view of the trial tray secured onto the resected tibia showing placement of a drill guide thereon.

#### Detailed Description of the Invention

5 While the invention is susceptible to various modifications and alternative forms, a specific embodiment thereof has been shown by way of example in the drawings and will herein be described in detail. It should be understood, however, that there is no intent to limit the invention to the particular form disclosed, but on the contrary, the intention  
10 is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the appended claims.

It should initially be appreciated that the present invention is used after proper resection of a patient's proximal tibia for evaluating the stability and kinematics of a mobile bearing implant therefor prior to  
15 committing to the final preparation of the proximal tibia. Proper resection of the proximal tibia is beyond the scope of the present disclosure.

Reference should be made to an appropriate surgical manual for such resection. In particular, reference is preferably made to the P.F.C.® Sigma Rotating Platform Knee System with M.B.T. Tray, copyright 2000,  
20 by DePuy International LTD, a Johnson & Johnson company, the disclosure of which is herein incorporated by reference in its entirety .

Referring now to Fig. 1, there is shown a trial tray assembly 10 having a trial tray 12 and a detachable alignment handle 14. The trial tray

12 has a body 25, preferably made of stainless steel, which is shaped to substantially correspond to the configuration of the patient's resected proximal tibia. The trial tray body 25 includes a cutout portion 32 that is partially surrounded by an inset ledge or rim 34. The cutout portion 32

5 includes a first radially extending slot 36 and a second radially extending slot 38. The inset ledge 34 is absent from the first and second radially extending slots 36 and 38. As explained further below, the cutout portion 32 and slots 36, 38 are configured and adapted to receive and retain an evaluation bullet.

10 The trial tray 25 also includes a first recessed bore 40 disposed proximate the slot 36 and a second recessed bore 42 disposed proximate the slot 38. The bores 40 and 42 are configured and adapted to receive fixation pins as explained below. In addition, the trial tray 25 includes a first slotted bore 26 in a sidewall thereof, and a second slotted bore 28 in

15 the sidewall thereof. A third bore 30 is disposed between the first and second slotted bores 26 and 28. These bores are adapted and configured to receive pins or prongs of the alignment handle 14 as described below.

The alignment handle 14 is defined by a stem 16 having a first

20 flanged pin or prong 20 and a second flanged pin or prong 22. The first and second flanged pins 20 and 22 are configured and adapted to be releasably received into the respective slotted bores 26 and 28 of the body 25 of the trial tray 12. The stem 16 also has a retractable center pin

24 that is configured and adapted to be received in the center bore 30 of the body 25 of the trial tray 12. A lever 18 controls the retraction and extension of the center pin 24.

For attachment of the handle 14 to the trial tray 12, the center pin 5 24 is retracted, and the flanged pins 20 and 22 are received into the slotted bores 26 and 28 respectively. Once the flanged pins 20 and 22 are received in the slotted bores 26 and 28, the center pin 24 is extended into the bore 30. The extension of the center pin 24 into the bore 30 prevents the flanged pins 20 and 22 from being removed from their 10 respective slotted bores 26 and 28. The lever 18 and/or the center pin 24 are preferably biased into an extended position. Removal of the handle 14 from the body 25 is accomplished in a reverse manner to installation or attachment thereof.

Referring to Fig. 2, the trial tray assembly 10 is shown placed onto 15 the patient's resected, proximal tibia 50. This is performed after resection of the proximal tibia, sizing of the trial tray 12, and attachment of the handle 14 to the trial tray 12. It should be appreciated that there are various sizes of trial trays to accommodate various sizes of a patient's tibia. Therefore, regardless of the size of the trial tray, the configuration 20 and function is the same as described herein for each size. The surgeon must decide which trial tray best fits the patient's resected, proximal tibia. The trial tray 12 is now ready to receive an evaluation bullet.

Referring now to Figs. 3-7, there is shown one embodiment of a tibia trial or evaluation bullet, generally designated 60, that may be used in conjunction with the trial tray assembly 10 during a total knee replacement surgery/operation. The evaluation bullet 60 is a fixed or non-rotation 5 (lock-off) evaluation bullet. As explained further below, the evaluation bullet 60 is used with a non-rotatable insert trial.

The evaluation bullet 60 is preferably made of stainless steel and is defined by a body 62. The shape of the body 62 is substantially the same as the shape of the cutout portion 32 of the trial tray 12. The body 62 also 10 has a first prong 64 and a second prong 66, each radially extending from therefrom in the same manner and substantially the same configuration as the slots 36 and 38 radially extend from the cutout portion 32. The body 62 further includes a trunnion 68 that defines a bearing surface for a trial insert 100 (see Fig. 14). The trunnion 68 is generally dome-shape in 15 cross section and includes a flat 70 on one side thereof. The flat 70 provides the non-rotational component of the bearing surface.

Referring to Figs. 8-12, there is shown another embodiment of a tibia trial or evaluation bullet, generally designated 80, that may be used in conjunction with the trial tray assembly 10 during a total knee replacement 20 surgery/operation. The evaluation bullet 80 is a rotational evaluation bullet. As explained further below, the evaluation bullet 60 is used with a rotatable insert trial.

The evaluation bullet 80 is preferably made of stainless steel and is defined by a body 82. The shape of the body 82 is substantially the same as the shape of the cutout portion 32 of the trial tray 12. The body 82 also has a first prong 84 and a second prong 86, each radially extending from 5 therefrom in the same manner and substantially the same configuration as the slots 36 and 38 radially extend from the cutout portion 32. The body 82 further includes a trunnion 88 that defines a bearing surface for a trial insert 110 (see Fig. 17). The trunnion 68 is generally arcuate-shaped in cross section and includes a concavity 90 on one side thereof. The 10 concavity 90 provides a rotational bearing surface for the trial insert 110. The first prong 84 includes a first mounting spike 85 extending therefrom while the second prong 86 includes a second mounting spike 87. As explained further below, the spikes 85 and 87 temporarily affix the evaluation bullet 80 onto the resected tibia 50 in order to allow the trial 15 insert 110 to rotate about the trunnion 88 by coaction between the trunnion 88/concavity 90 and the trial insert 110.

It should be appreciated that the two embodiments of the evaluation bullets 60 and 80 respectively shown in Figs. 3-7, and 8-12, are for use during performance of a joint replacement procedure such as a 20 total knee replacement procedure. Therefore, although the present invention is herein exemplarily described in regard to performance of a total knee replacement procedure, certain of the concepts of the present

invention may be utilized in regard to replacement procedures at numerous other joint locations throughout the body.

Referring to Fig. 13, the evaluation bullet 60 is shown being inserted into the cutout portion 32 of the body 25 of the trial tray 12 after 5 the trial tray assembly 10 is positioned onto the resected tibia 50. At this point, the trial tray assembly 10, which now includes the evaluation bullet 60, is ready to receive an insert trial that allows the surgeon to check the stability of the final implant.

Referring to Fig. 14, there is shown an insert trial 100 having a 10 recess 102, being inserted onto the trunnion 68 of the evaluation bullet 60. The insert trial 100 is chosen to match the femoral size and style, and one that is either curved or stabilized, per the surgeon's preference. The recess 102 of the insert trial 100 is received on the trunnion 68 in a non-rotatable manner. When the insert trial 100 is in place, the knee of the 15 patient is carefully extended, noting the anteroposterior stability, medial/lateral stability and overall alignment in the A/P and M/L plane. Various insert trials may be tried in order to ascertain which final implant will work best.

Referring to Fig. 15, rotational alignment of the tibial tray 25 is 20 adjusted with the knee in full extension, using the handle 16 to rotate the tray 25 and insert trial 100 into congruency with the femoral trial 140. The rotation of the trial tray 25 is usually centered on the junction between the medial and central one-third of the tibial tubercle. Once the appropriate

position is located, it is marked 96 by electrocautery tool 94 on the anterior tibial cortex. Overall alignment may be confirmed using a two part alignment rod, attaching it to the handle 16.

The trial reduction explained above with reference to a non-rotating 5 insert trial, may be accomplished with a rotating insert trial instead of or in addition to the non-rotating insert trial. This is accomplished by using the evaluation bullet 80 (a "pinned" evaluation bullet) rather than the evaluation bullet 60. In this regard, reference is now made to Fig. 16. In Fig. 16, the evaluation bullet 60 is shown being inserted into the cutout 10 portion 32 of the tray body 25 of the trial tray 12. The evaluation bullet 80 is tapped down to push the spikes 85 and 87 into the proximal tibia.

Once the evaluation bullet 80 is in place, a tibial insert trial 110 is chosen that matches the chosen femoral size and style, curved or stabilized, as decided by the surgeon for the particular case and anatomy. 15 Referring to Figs. 17 and 18, the insert trial 110 includes a recess 112 that is received onto the trunnion 88 of the evaluation bullet 80. As well, the handle 16 is removed. With the trial insert 110 in place, the knee is extended noting the anteroposterior stability, medial/lateral stability and overall alignment in the A/P and M/L plane. Assessment of the bearing 20 rotation and patellofemoral tracking can also be achieved, since the insert trial 110 is rotatable on the trunnion 88/evaluation bearing 80. Overall alignment can be confirmed using a two part alignment rod (not shown) attaching it to the handle 16 that would be reattached to the trial tray 25.

If there is any indication of instability, a next greater thickness insert trial is selected and trial reduction is repeated. An insert trial should be selected which gives the greatest stability in flexion and extension while still allowing full extension. Once the correct insert trial is obtained, tray

5 rotation and position is noted and marked with electrocautery.

Referring to Figs. 19 and 20, thereafter, the handle 16 is reattached to the tray 25 and the evaluation bullet is removed (for both evaluation bullets 60 and 80). The trial tray 12 is then secured to the tibia 50 by two fixation pins 120 and 122 respectively extending through recessed bores

10 40 and 42. The handle 16 is then removed and a drill guide 130 is retained thereon. Various options regarding the final implant vary from cemented to non-cemented applications, as well as with or without keel preparation. After drilling or the like, the trial tray 25 is removed and the final implant is installed.

15 Please note that the trunnion 88 of the evaluation bullet 80 is configured to cooperate with the structure of the insert trial 110 that defines the recess 112 so as to enable rotation of the insert trial 110 about a fixed axis relative to the evaluation bullet. However, it should be appreciated that the trunnion 88 of the evaluation bullet 80 and the

20 structure of the insert trial 110 that defines the recess 112 may be alternatively configured. With such configuration, the alternatively configured trunnion would be configured to cooperate with the alternatively configured structure of the insert trial that defines the recess

so as to enable some anterior-posterior movement (and/or medial-lateral movement) along with some rotational movement of the insert trial relative to the evaluation bullet.

5

### Operation of the Present Invention

In operation, the trial tray assembly 10 of the present invention is utilized to evaluate and check the kinematics of a patient's tibia 50 for implantation of a tibial component during performance of a knee replacement procedure. In order to do so, the proximal end portion of the patient's tibia 50 is first resected by use of, for example, a bone saw (not shown). Thereafter, with the knee in maximal flexion, the patient's tibia 50 is subluxed anteriorly with a tibia retractor (not shown). An appropriately sized trial tray 12, having a handle assembly 14 is placed onto the resected tibia 50, as particularly shown in Figs. 2, 13, and 16. In particular, a group of trial trays 12 may be provided which includes trial trays configured in a number of different sizes. Hence, a trial tray 12 which provides the greatest coverage of the resected surface of the tibia 50 without overhanging anteriorly of the midcoronal plane of the tibia 50 is selected from such a group.

20

An appropriate evaluation bullet 60 or 80 is selected and placed into the cutout portion 32 of the tray body 25. If a non-rotating insert trial is desired, the evaluation bullet 60 is chosen. If a rotating insert trial is desired, the evaluation bullet 80 is chosen. An appropriate insert trial is

then placed onto the trunnion of the evaluation bullet. Once the bullet and insert trial are in place, the knee is extended in order to allow the surgeon to assess the medial and lateral stability of the knee along with the overall alignment of the knee in both the anterior/posterior and medial/lateral planes. If the surgeon encounters any potential instability, a different insert trial 100 or 110 may be substituted in order increase stability in flexion and extension along with allowing for full extension.

Moreover, during such a "mock up", the surgeon may adjust the rotational alignment of the trial tray 12 while the knee is positioned in full extension. The handle assembly 16 is utilized to rotate the trial tray 12 and the bearing insert 110 relative to the femoral component 140. Once each of the components associated with the prostheses is positioned in a desired location, the location of the trial tray 12 is marked so as to be recreated at a later time. In particular, as shown in FIG. 15, electrocautery is utilized to create a number of alignment marks 96 on the anterior tibial cortex of the patient's tibia 50. Such marks 96 correspond with features on the trial tray 12 and/or the handle assembly 16 thereby allowing the current orientation of the trial tray 12 to be reproduced by subsequent realignment of the trial tray 12 relative to the marks 96. Once the alignment marks 96 have been formed in the tibia 50, the trial prostheses may be disassembled or otherwise removed from the knee.

Thereafter, with the knee in substantially full flexion and the tibia subluxed anteriorly, the trial tray 12 is positioned in a desired rotational

position by use of the alignment marks 96. Once aligned, the evaluation bullet is removed and the trial tray 12 is secured to the resected surface of the tibia 50 by use of the fixation pins 120, 122 which are inserted through the openings 40, 42 defined in the plate 25 of the trial tray 12. It should

5 be appreciated that a pair of holes (not shown) may be drilled in the tibia 50 to receive the fixation pins 120, 122 prior to insertion thereof.

The handle assembly 16 which was utilized to align the trial tray 12 is then removed so that the handle assembly 16 associated with the drill guide 130 may be secured to the trial tray 12. Once the drill guide 130

10 has been secured to the trial tray 12, a bone drill (not shown) is advanced through an elongated bore of the drill guide 130 in order to drill a drilled hole in the patient's tibia 50. The bone drill (not shown) may be equipped with a depth stop which engages the body of the drill guide 130 once the bone drill has drilled to a desired depth in the patient's tibia 50. It should

15 be appreciated that the drilled hole is provided to receive a sub-stem member of a final tibial component. As such, it should further be appreciated that the drilled hole is centered or otherwise aligned with the both the center of the plate 25 of the trial tray 12 (i.e. the center point of the plate opening 32) and the center of the tibia 50.

20 The trial tray 25 is used as a drill/broach guide and an appropriate bore is made in the tibia 50 for the final implant. Once broached or punched in such a manner, the trial assembly may be disassembled. The fixation pins 120, 122 may then be removed so as to allow the trial tray 12

to be detached from the tibia 50. The resultant features formed in the proximal end of the patient's tibia 50 are configured to receive a final tibial implant 100.

While the invention has been illustrated and described in detail in  
5 the drawings and foregoing description, such an illustration and  
description is to be considered as exemplary and not restrictive in  
character; it being understood that only the preferred embodiment has  
been shown and described and that all changes and modifications that  
come within the spirit of the invention are desired to be protected. For  
10 example, while the evaluation bullet is disclosed as being adapted to  
removably fit into a configured recess in the trial tray, it is possible that the  
evaluation bullet can be made integral with the trial tray.

There is a plurality of advantages of the present invention arising  
from the various features of the present invention and associated method  
15 described herein. It will be noted that alternative embodiments of the  
surgical instrument assembly and associated method of the present  
invention may not include all of the features described yet still benefit from  
at least some of the advantages of such features. Those of ordinary skill  
in the art may readily devise their own implementations of a surgical  
20 instrument assembly and associated method that incorporate one or more  
of the features of the present invention and fall within the spirit and scope  
of the present invention as defined by the appended claims.